

REMARKS

Review and reconsideration on the merits are requested.

Status of Claims

Claims 1-19 are presented for examination.

The prior art

U.S. 6,538,152 Tanaka et al (Tanaka); U.S. 6,720,014 Short et al (Short); U.S. 6,262,115 Guittard et al (Guittard).

The Sole Rejection

Claims 1-19 under 35 U.S.C. § 103(a) as being unpatentable over Tanaka in view of Short and Guittard.

The Examiner's position is set forth in the Action and will not be repeated here except as necessary to an understanding of Applicants' traversal which is now presented.

Traversal

Guittard

To fully understand the Examiner's position, it is necessary at times to refer to the Action of 10/20/2006 and the present Action of 07/16/2007.

In the Action of 10/20/2006 at page 5, the Examiner states:

"[T]he art has recognized the overactive bladder and urinary incontinence as synonymous (e.g., see Guittard et al. who teaches "Involuntary incontinence *also known as urge incontinence and overactive bladder...*", col. 1, lines 55-56). Italics added.

Referring now to the Action of 07/16/2007, page 3, the Examiner states:

"Respecting the secondary references, Short and Guittard, they remain properly cited for the purpose relied on by the Examiner, i.e., for showing that (i) urinary incontinence is a

symptom of overactive bladder and (ii) that overactive bladder and urinary incontinence are synonymous, respectively.”

Although the Examiner considers overactive bladder (OAB) as synonymous to urinary incontinence based on Guittard, col. 1, lines 55-56, Guittard actually stated (underscore added):

“Involuntary incontinence also known as urge incontinence and overactive bladder, occurs with a loss of a large volume of urine accompanied by symptoms of urgency, frequency and nocturia caused by an unstable bladder or detrusor instability.” (Col. 1, lines 55-59) and

“Urinary incontinence is also known as overactive bladder with symptoms of urinary frequency or urge incontinence.” (Col. 1, lines 63-65).

Referring to the underlined portions in these two quotations from Guittard, it is seen that Guittard is inconsistent regarding the relationship between overactive bladder and urge incontinence. (see the underlined material from the above quotations).

According to the second sentence, “urinary incontinence” is taught as including only symptoms accompanied by “urinary frequency”.

This is contrary disclosure as “urinary incontinence” is a symptom accompanied by incontinence.

Applicants advise, for reference, that in the disclosure of the corresponding PCT application, WO 96/37202, Guittard uses different language:

“Involuntary incontinence also known as urge incontinence occurs with a loss of a large volume of urine accompanied by symptoms of urgency, frequency and nocturia caused by an unstable bladder or detrusor instability”. (See page 2, lines 4-6).

This disclosure does not appear contradictory as in the U.S. version of Guittard.

In detail, before filing the present application, OAB was clearly defined as a syndrome of urgency, with or without incontinence, usually with frequency and nocturia. This is according to the standardization of terminology reported by the International Continence Society, *Neurourology and Urodynamics*, Vol. 21, pp. 167-178, 2002, especially at page 170, left column, lines 1-4 from the bottom (see the attached copy). This is described in the present specification at page 1, lines 17-22:

“According to the new terminology of the International Continence Society published in 2002, OAB is diagnosed symptomatically. The symptoms of OAB are imperative urinary urgency with or without urge incontinence, generally but not necessarily combined with pollakisuria and nocturia. OAB is also characterized by involuntary detrusor contractions which are either triggered by provocation or occur spontaneously.”

Since 2002, the terminology of the International Continence Society has generally been used.

In more detail, *Neurourology and Urodynamics* - hereafter *Standardization* - was published in 2002 and has been titled: *The Standardization of Terminology of Lower Urinary Tract Function: Report from the Standardization Sub-committee of the International Continence Society*.

The definitions therein were written to be compatible with the WHO publication and ICD 10, the International classification of diseases. See page 167, left column, fourth full paragraph. It is reasonable to conclude that *Standardization* was to benefit the medical community by providing standard terminology dealing with the lower urinary tract function. Referring to page 171, left column, the last full paragraph, the following definition occurs:

- Urgency, with or without urge incontinence, usually with frequency and nocturia, can be described as the *overactive bladder syndrome, urge syndrome or urinary-frequency syndrome (NEW)*

Thus, using standard terminology for lower urinary tract function, the above definition establishes that in overactive bladder (OAB) syndrome, “urgency” is different from “urinary incontinence” and “frequency”, and is seen independently of whether urinary incontinence and/or pollakiuria coexist or not.

This is often used when explaining OAB, using language such as “OAB is a syndrome of urgency, with or without urge incontinence, usually with frequency and nocturia”.

Thus, the definition means that when someone were to read the above definition, which represents standard terminology, that at least urgency occurs in OAB, that person would understand that in OAB “urgency” is different from “urinary incontinence” and “frequency”, and is seen independently of whether or not urinary incontinence and/or pollakiuria coexist or not.

Applicant submit that the above explanation is reasonable and logical on all points.

They thus submit that the Examiner’s reading of the prior art is an incorrect reading of the prior art, and the present claims stand patentable over the prior art.

In short, to one of ordinary skill in the art, the clear teaching urged by the Examiner in Guittard is not found.

Short

As the Examiner states, Action of 10/20/2006, paragraph bridging pages 4/5, Short does disclose that oxybutynin is an agent for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency. See Table 2 of Short at cols. 65/66, where

this is an accurate quotation of the Product Detropan® XL (Oxybutynin Chloride) under Description.

Despite this, however, there is no specific disclosure about the effect of urgency in OAB patients.

Tanaka

As the Examiner states, Tanaka does simply disclose that the compounds of the present invention have a relaxing effect on the human bladder and are useful for the prevention or treatment of pollakiuria and urinary incontinence.

The Present Invention and Unobviousness

In distinction to the above, the present invention is based on a novel different effect on spontaneous small bladder contractions.

The above definition from Standardization provides an OAB “urgency” is different from “urinary incontinence” and “frequency”, and is seen independently of whether or not urinary incontinence and/or pollakiuria exist or not.

In addition, urgency can mainly be attributed to spontaneous small bladder contraction.

This means that the inhibitory effect on spontaneous small bladder contractions is not necessarily shown or exhibited by a relaxing effect on bladder smooth muscle as described in Tanaka.

Further, the oxybutynin described in Guittard exerts its desired effects based on the anti-muscarinic effect, not a β_3 -adrenoceptor stimulating effect as the compounds of the present invention. Thus, oxybutynin is distinctly different in effects on the urinary bladder from the compounds of the present invention. This can be easily understood from the results of Example 1 herein showing that while the compounds of the present invention exert a direct relaxing effect

on urinary bladder smooth muscle, oxybutynin or the like does not significantly exert such a direct relaxing effect.

Applicants thus submit one of ordinary skill in the art would not be led to combine Tanaka with Guittard/Short to reach the present invention.

The Examiner's attention is further directed to Example 4 herein.

Example 4 shows that the present compounds exert a stronger inhibitory effect of spontaneous small bladder contraction than tolterodine, an anti-muscarinic drug, but do not effect micturition pressure, and are excellent agents.

Applicants respectfully submit that the effects of the compounds of the present invention would be unobvious from the effects of oxybutynin which exert its effects obtained by a different mechanism.

Conclusion

In conclusion, the present invention is directed to a method of treating *urinary urgency associated with overactive bladder*. It is submitted to be unobvious from the prior art relied upon by the Examiner.

Request for Telephone Interview

After the Examiner has had an opportunity to consider this response, Applicants by way of Counsel respectfully request a telephone interview.

Claim Amendments

The claims are amended to specifically recite that the present invention is directed to a method of treating urinary urgency associated with overactive bladder which comprises administering...

On basis see, for example, page 1, line 9, page 1, lines 18/19, page 2, lines 19-22, etc.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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The Standardisation of Terminology of Lower Urinary Tract Function: Report from the Standardisation Sub-committee of the International Continence Society

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This report presents definitions of the symptoms, signs, urodynamic observations and conditions associated with lower urinary tract dysfunction (LUTD) and urodynamic studies (UDS), for use in all patient groups from children to the elderly.

The definitions restate or update those presented in previous International Continence Society Standardisation of Terminology reports (see references) and those shortly to be published on Urethral Function [Lose et al., in press] and Nocturia [van Kerrebroeck et al., 2002]. The published ICS report on the technical aspects of urodynamic equipment [Rowan et al., 1987] will be complemented by the new ICS report on urodynamic practice to be published shortly [Schäfer et al., 2002]. In addition there are four published ICS outcome reports [Fonda et al., 1998; Lose et al., 1998; Mattiasson et al., 1998; Nordling et al., 1998].

New or changed definitions are all indicated, however, recommendations concerning technique are not included in the main text of this report.

The definitions have been written to be compatible with the WHO publication ICDH-2 [International Classification of Functioning, Disability and Health] published in 2001 and ICD10, the International Classification of Diseases. As far as possible, the definitions are descriptive of observations, without implying underlying assumptions that may later prove to be incorrect or incomplete. By following this principle the International Continence Society (ICS) aims to facilitate comparison of results and enable effective communication by investigators who use urodynamic methods. This report restates the ICS principle that symptoms, signs and conditions are separate categories, and adds a category of urodynamic observations. In addition, terminology related to therapies is included [Andersen et al., 1992].

When a reference is made to the whole anatomical organ the vesica urinaria, the correct term is the bladder. When the smooth muscle structure known as the m.detrusor urinae is being discussed, then the correct term is detrusor.

It is suggested that acknowledgement of these standards in written publications be indicated by a footnote to the section "Methods and Materials" or its equivalent, to read as follows:

"Methods, definitions and units conform to the standards recommended by the International Continence Society, except where specifically noted".

The report covers the following areas:

LOWER URINARY TRACT SYMPTOMS (LUTS)

Symptoms are the subjective indicator of a disease or change in condition as perceived by the patient, carer or partner and may lead him/her to seek help from health care professionals. (NEW)

Symptoms may either be volunteered or described during the patient interview. They are usually qualitative. In general, Lower Urinary Tract Symptoms cannot be used to make a definitive diagnosis. Lower Urinary Tract Symptoms can also indicate pathologies other than lower urinary tract dysfunction, such as urinary infection.

SIGNS SUGGESTIVE OF LOWER URINARY TRACT DYSFUNCTION (LUTD)

Signs are observed by the physician including simple means, to verify symptoms and quantify them. (NEW)

For example, a classical sign is the observation of leakage on coughing. Observations from frequency volume charts, pad tests and validated symptom and quality of life questionnaires are examples of other instruments that can be used to verify and quantify symptoms.

URODYNAMIC OBSERVATIONS

Urodynamic observations are observations made during urodynamic studies. (NEW)

For example, an involuntary detrusor contraction (detrusor overactivity) is a urodynamic observation. In general, a urodynamic observation may have a number of possible underlying

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causes and does not represent a definitive diagnosis of a disease or condition and may occur with a variety of symptoms and signs, or in the absence of any symptoms or signs.

CONDITIONS

Conditions are defined by the presence of urodynamic observations associated with characteristic symptoms or signs and/or non-urodynamic evidence of relevant pathological processes. (NEW)

TREATMENT

Treatment for lower urinary tract dysfunction: these definitions are from the 7th ICS report on Lower Urinary Tract Rehabilitation Techniques [Andersen et al., 1992].

1. LOWER URINARY TRACT SYMPTOMS (LUTS)

Lower urinary tract symptoms are defined from the individual's perspective, who is usually, but not necessarily a patient within the healthcare system. Symptoms are either volunteered by, or elicited from, the individual or may be described by the individual's caregiver.

Lower urinary tract symptoms are divided into three groups, storage, voiding, and post micturition symptoms.

1.1 Storage symptoms are experienced during the storage phase of the bladder, and include daytime frequency and nocturia. (NEW)

- **Increased daytime frequency** is the complaint by the patient who considers that he/she voids too often by day. (NEW) This term is equivalent to pollakisuria used in many countries.
- **Nocturia** is the complaint that the individual has to wake at night one or more times to void. (NEW)¹
- **Urgency** is the complaint of a sudden compelling desire to pass urine, which is difficult to defer. (CHANGED)
- **Urinary incontinence** is the complaint of any involuntary leakage of urine. (NEW)²

In each specific circumstance, urinary incontinence should be further described by specifying relevant factors such as type, frequency, severity, precipitating factors, social impact, effect on

hygiene and quality of life, the measures used to contain the leakage, and whether or not the individual seeks or desires help because of urinary incontinence.³

Urinary leakage may need to be distinguished from sweating or vaginal discharge.

- **Stress urinary incontinence** is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. (CHANGED)⁴
- **Urge urinary incontinence** is the complaint of involuntary leakage accompanied by or immediately preceded by urgency. (CHANGED)⁵
- **Mixed urinary incontinence** is the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing. (NEW)
- **Enuresis** means any involuntary loss of urine. (ORIGINAL) If it is used to denote incontinence during sleep, it should always be qualified with the adjective "nocturnal".
- **Nocturnal enuresis** is the complaint of loss of urine occurring during sleep. (NEW)
- **Continuous urinary incontinence** is the complaint of continuous leakage. (NEW)
- **Other types of urinary incontinence** may be situational, for example the report of incontinence during sexual intercourse, or giggle incontinence.
- **Bladder sensation** can be defined, during history taking, by five categories.

Normal: the individual is aware of bladder filling and increasing sensation up to a strong desire to void. (NEW)

Increased: the individual feels an early and persistent desire to void. (NEW)

Reduced: the individual is aware of bladder filling but does not feel a definite desire to void. (NEW)

Absent: the individual reports no sensation of bladder filling or desire to void. (NEW)

Non-specific: the individual reports no specific bladder sensation, but may perceive bladder filling as abdominal fullness, vegetative symptoms, or spasticity. (NEW)⁶

1.2 Voiding symptoms are experienced during the voiding phase. (NEW)

¹The term night time frequency differs from that for nocturia, as it includes voids that occur after the individual has gone to bed, but before he/she has gone to sleep; and voids which occur in the early morning which prevent the individual from getting back to sleep as he/she wishes. These voids before and after sleep may need to be considered in research studies, for example, in nocturnal polyuria. If this definition were used then an adapted definition of daytime frequency would need to be used with it.

²In infants and small children the definition of Urinary Incontinence is not applicable. In scientific communications the definition of incontinence in children would need further explanation.

³The original ICS definition of incontinence, "Urinary incontinence is the involuntary loss of urine that is a social or hygienic problem", relates the complaint to quality of life (QoL) issues. Some QoL instruments have been, and are being, developed in order to assess the impact of both incontinence and other LUTS on QoL.

⁴The committee considers the term "stress incontinence" to be unsatisfactory in the English language because of its mental connotations. The Swedish, French and Italian expression "effort incontinence" is preferable, however, words such as "effort" or "exertion" still do not capture some of the common precipitating factors for stress incontinence such as coughing or sneezing. For this reason the term is left unchanged.

⁵Urge incontinence can present in different symptomatic forms, for example, as frequent small losses between micturitions, or as a catastrophic leak with complete bladder emptying.

⁶These non-specific symptoms are most frequently seen in neurological patients, particularly those with spinal cord trauma and in children and adults with malformations of the spinal cord.

- **Slow stream** is reported by the individual as his or her perception of reduced urine flow, usually compared to previous performance or in comparison to others. (NEW)
- **Splitting or spraying** of the urine stream may be reported. (NEW)
- **Intermittent stream (Intermittency)** is the term used when the individual describes urine flow, which stops and starts, on one or more occasions, during micturition. (NEW)
- **Hesitancy** is the term used when an individual describes difficulty in initiating micturition resulting in a delay in the onset of voiding after the individual is ready to pass urine. (NEW)
- **Straining** to void describes the muscular effort used to either initiate, maintain or improve the urinary stream. (NEW)⁷
- **Terminal dribble** is the term used when an individual describes a prolonged final part of micturition, when the flow has slowed to a trickle/dribble. (NEW)

1.3 Post micturition symptoms are experienced immediately after micturition. (NEW)

- **Feeling of incomplete emptying** is a self-explanatory term for a feeling experienced by the individual after passing urine. (NEW)
- **Post micturition dribble** is the term used when an individual describes the involuntary loss of urine immediately after he or she has finished passing urine, usually after leaving the toilet in men, or after rising from the toilet in women. (NEW)

1.4 Symptoms Associated with Sexual Intercourse

Dyspareunia, vaginal dryness and incontinence are amongst the symptoms women may describe during or after intercourse. These symptoms should be described as fully as possible. It is helpful to define urine leakage as: during penetration, during intercourse, or at orgasm.

1.5 Symptoms Associated with Pelvic Organ Prolapse

The feeling of a lump ("something coming down"), low backache, heaviness, dragging sensation, or the need to digitally replace the prolapse in order to defaecate or micturate, are amongst the symptoms women may describe who have a prolapse.

1.6 Genital and Lower Urinary Tract Pain⁸

Pain, discomfort and pressure are part of a spectrum of abnormal sensations felt by the individual. Pain produces the

greatest impact on the patient and may be related to bladder filling or voiding, may be felt after micturition, or be continuous. Pain should also be characterised by type, frequency, duration, precipitating and relieving factors and by location as defined below:

- **Bladder pain** is felt suprapubically or retropubically, usually increases with bladder filling, and may persist after voiding. (NEW)
- **Urethral pain** is felt in the urethra and the individual indicates the urethra as the site. (NEW)
- **Vulval pain** is felt in and around the external genitalia. (NEW)
- **Vaginal pain** is felt internally, above the introitus. (NEW)
- **Scrotal pain** may or may not be localised, for example to the testis, epididymis, cord structures or scrotal skin. (NEW)
- **Perineal pain** is felt: in the female, between the posterior fourchette (posterior lip of the introitus) and the anus, and in the male, between the scrotum and the anus. (NEW)
- **Pelvic pain** is less well defined than, for example, bladder, urethral or perineal pain and is less clearly related to the micturition cycle or to bowel function and is not localised to any single pelvic organ. (NEW)

1.7 Genito-Urinary Pain Syndromes and Symptom Syndromes Suggestive of LUTD

Syndromes describe constellations, or varying combinations of symptoms, but cannot be used for precise diagnosis. The use of the word syndrome can only be justified if there is at least one other symptom in addition to the symptom used to describe the syndrome. In scientific communications the incidence of individual symptoms within the syndrome should be stated, in addition to the number of individuals with the syndrome.

The syndromes described are functional abnormalities for which a precise cause has not been defined. It is presumed that routine assessment (history taking, physical examination, and other appropriate investigations) has excluded obvious local pathologies, such as those that are infective, neoplastic, metabolic or hormonal in nature.

1.7.1 Genito-urinary pain syndromes are all chronic in their nature. Pain is the major complaint but concomitant complaints are of lower urinary tract, bowel, sexual or gynaecological nature.

⁷Suprapubic pressure may be used to initiate or maintain urine flow. The Credé manoeuvre is used by some spinal cord injury patients, and girls with detrusor underactivity sometimes press suprapubically to help empty the bladder.

⁸The terms "strangury", "bladder spasm", and "dysuria" are difficult to define and of uncertain meaning and should not be used in relation to lower urinary tract dysfunction, unless a precise meaning is stated. Dysuria literally means 'abnormal urination', and is used correctly in some European countries however, it is often used to describe the stinging/burning sensation characteristic of urinary infection. It is suggested that these descriptive words should not be used in future.

- **Painful bladder syndrome** is the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms such as increased daytime and night-time frequency, in the absence of proven urinary infection or other obvious pathology. (NEW)⁹
- **Urethral pain syndrome** is the occurrence of recurrent episodic urethral pain usually on voiding, with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology. (NEW)
- **Vulval pain syndrome** is the occurrence of persistent or recurrent episodic vulval pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology. (NEW)¹⁰
- **Vaginal pain syndrome** is the occurrence of persistent or recurrent episodic vaginal pain which is associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven vaginal infection or other obvious pathology.
- **Scrotal pain syndrome** is the occurrence of persistent or recurrent episodic scrotal pain which is associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven epididymo-orchitis or other obvious pathology.
- **Perineal pain syndrome** is the occurrence of persistent or recurrent episodic perineal pain, which is either related to the micturition cycle or associated with symptoms suggestive of urinary tract or sexual dysfunction. There is no proven infection or other obvious pathology. (NEW)¹¹
- **Pelvic pain syndrome** is the occurrence of persistent or recurrent episodic pelvic pain associated with symptoms suggestive of lower urinary tract, sexual, bowel or gynaecological dysfunction. There is no proven infection or other obvious pathology. (NEW)

1.7.2. Symptom syndromes suggestive of lower urinary tract dysfunction

In clinical practice, empirical diagnoses are often used as the basis for initial management after assessing the individual's lower urinary tract symptoms, physical findings and the results of urinalysis and other indicated investigations.

- **Urgency**, with or without urge incontinence, usually with frequency and nocturia, can be described as the overactive bladder syndrome, urge syndrome or urgency-frequency syndrome. (NEW)

These symptom combinations are suggestive of urodynamically demonstrable detrusor overactivity, but can be due to other forms of urethro-vesical dysfunction. These terms can be used if there is no proven infection or other obvious pathology.

- **Lower urinary tract symptoms suggestive of bladder outlet obstruction** is a term used when a man complains predominately of voiding symptoms in the absence of infection or obvious pathology other than possible causes of outlet obstruction. (NEW)¹²

2. SIGNS SUGGESTIVE OF LOWER URINARY TRACT DYSFUNCTION (LUTD)

2.1 Measuring the Frequency, Severity and Impact of Lower Urinary Tract Symptoms

Asking the patient to record micturitions and symptoms¹³ for a period of days provides invaluable information. The recording of micturition events can be in three main forms:

- **Micturition time chart:** this records only the times of micturitions, day and night, for at least 24 hours. (NEW)
- **Frequency volume chart (FVC):** this records the volumes voided as well as the time of each micturition, day and night, for at least 24 hours. (CHANGED)
- **Bladder diary:** this records the times of micturitions and voided volumes, incontinence episodes, pad usage and other information such as fluid intake, the degree of urgency and the degree of incontinence. (NEW)¹⁴

The following measurements can be abstracted from frequency volume charts and bladder diaries:

- **Daytime frequency** is the number of voids recorded during waking hours and includes the last void before sleep and the first void after waking and rising in the morning. (NEW)
- **Nocturia** is the number of voids recorded during a night's sleep: each void is preceded and followed by sleep. (NEW)
- **24-hour frequency** is the total number of daytime voids and episodes of nocturia during a specified 24-hour period. (NEW)
- **24-hour production** is measured by collecting all urine for 24-hours. (NEW)

⁹The ICS believes this to be a preferable term to "interstitial cystitis". Interstitial cystitis is a specific diagnosis and requires confirmation by typical cystoscopic and histological features. In the investigation of bladder pain it may be necessary to exclude conditions such as carcinoma in situ and endometriosis.

¹⁰The ICS suggests that the term vulvodynia (vulva – pain) should not be used, as it leads to confusion between single symptom and a syndrome.

¹¹The ICS suggests that in men, the term prostatodynia (prostate-pain) should not be used as it leads to confusion between a single symptom and a syndrome.

¹²In women voiding symptoms are usually thought to suggest detrusor underactivity rather than bladder outlet obstruction.

¹³Validated questionnaires are useful for recording symptoms, their frequency, severity and bother, and the impact of LUTS on QoL. The instrument used should be specified.

¹⁴It is useful to ask the individual to make an estimate of liquid intake. This may be done precisely by measuring the volume of each drink or crudely by asking how many drinks are taken in a 24-hour period. If the individual eats significant quantities of water containing foods (vegetables, fruit, salads) then an appreciable effect on urine production will result. The time that diuretic therapy is taken should be marked on a chart or diary.

This is usually commenced after the first void produced after rising in the morning, and is completed by including the first void on rising the following morning.

- **Polyuria** is defined as the measured production of more than 2.8 litres of urine in 24 hours in adults. It may be useful to look at output over shorter time frames [van Kerrebroeck et al., 2002]. (NEW)¹⁵
- **Nocturnal urine volume** is defined as the total volume of urine passed between the time the individual goes to bed with the intention of sleeping and the time of waking with the intention of rising. (NEW) Therefore, it excludes the last void before going to bed but includes the first void after rising in the morning.
- **Nocturnal polyuria** is present when an increased proportion of the 24-hour output occurs at night (normally during the 8 hours whilst the patient is in bed). (NEW) The night time urine output excludes the last void before sleep but includes the first void of the morning.¹⁶
- **Maximum voided volume** is the largest volume of urine voided during a single micturition and is determined either from the frequency/volume chart or bladder diary. (NEW)

The maximum, mean and minimum voided volumes over the period of recording may be stated.¹⁷

2.2 Physical examination is essential in the assessment of all patients with lower urinary tract dysfunction. It should include abdominal, pelvic, perineal and a focussed neurological examination. For patients with possible neurogenic lower urinary tract dysfunction, a more extensive neurological examination is needed.

2.2.1 Abdominal: the bladder may be felt by abdominal palpation or by suprapubic percussion. Pressure suprapubically or during bimanual vaginal examination may induce a desire to pass urine.

2.2.2 Perineal / genital inspection allows the description of the skin, for example the presence of atrophy or excoriation, any abnormal anatomical features and the observation of incontinence.

- **Urinary incontinence (the sign)** is defined as urine leakage seen during examination: this may be urethral or extraurethral.

- **Stress urinary incontinence** is the observation of involuntary leakage from the urethra, synchronous with exertion/effort, or sneezing or coughing. (CHANGED)¹⁸

Stress Leakage is presumed to be due to raised abdominal pressure.

- **Extra-urethral incontinence** is defined as the observation of urine leakage through channels other than the urethra. (ORIGINAL)
- **Uncategorised incontinence** is the observation of involuntary leakage that cannot be classified into one of the above categories on the basis of signs and symptoms. (NEW)

2.2.3 Vaginal examination allows the description of observed and palpable anatomical abnormalities and the assessment of pelvic floor muscle function, as described in the ICS report on Pelvic Organ Prolapse. The definitions given are simplified versions of the definitions in that report. [Bump et al., 1996]

- **Pelvic organ prolapse** is defined as the descent of one or more of: the anterior vaginal wall, the posterior vaginal wall, and the apex of the vagina (cervix/uterus) or vault (cuff) after hysterectomy. Absence of prolapse is defined as stage 0 support; prolapse can be staged from stage I to stage IV. (NEW)

Pelvic organ prolapse can occur in association with urinary incontinence and other lower urinary tract dysfunction and may on occasion mask incontinence.

- **Anterior vaginal wall prolapse** is defined as descent of the anterior vagina so that the urethrovesical junction (a point 3cm proximal to the external urinary meatus) or any anterior point proximal to this is less than 3cm above the plane of the hymen. (CHANGED)
- **Prolapse of the apical segment of the vagina** is defined as any descent of the vaginal cuff scar (after hysterectomy) or cervix, below a point which is 2cm less than the total vaginal length above the plane of the hymen. (CHANGED)
- **Posterior vaginal wall prolapse** is defined as any descent of the posterior vaginal wall so that a midline point on the posterior vaginal wall 3cm above the level of the hymen or any posterior point proximal to this, is less than 3 cm above the plane of the hymen. (CHANGED)

2.2.4 Pelvic floor muscle function can be qualitatively defined by the tone at rest and the strength of a voluntary or reflex contraction as strong, weak or absent or by a validated grading system (e.g. Oxford 1-5). A pelvic muscle contraction may be assessed by

¹⁵The causes of polyuria are various and reviewed elsewhere but include habitual excess fluid intake. The figure of 2.8 is based on a 70kg person voiding >40ml/kg.

¹⁶The normal range of nocturnal urine production differs with age and the normal ranges remain to be defined. Therefore, nocturnal polyuria is present when greater than 20% (young adults) to 33% (over 65 years) is produced at night. Hence the precise definition is dependant on age.

¹⁷The term "functional bladder capacity" is no longer recommended as "voided volume" is a clearer and less confusing term, particular if qualified e.g. 'maximum voided volume'. If the term bladder capacity is used, in any situation, it implies that this has been measured in some way, if only by abdominal ultrasound. In adults, voided volumes vary considerably. In children, the "expected volume" may be calculated from the formula (30+ (age in years × 30) in ml). Assuming no residual urine this will be equal to the "expected bladder capacity".

¹⁸Coughing may induce a detrusor contraction, hence the sign of stress incontinence is only a reliable indication of urodynamic stress incontinence when leakage occurs synchronously with the first proper cough and stops at the end of that cough.

visual inspection, by palpation, electromyography or perineometry. Factors to be assessed include strength, duration, displacement, and repeatability.

2.2.5 Rectal examination allows the description of observed and palpable anatomical abnormalities and is the easiest method of assessing pelvic floor muscle function in children and men. In addition, rectal examination is essential in children with urinary incontinence to rule out faecal impaction.

- **Pelvic floor muscle function** can be qualitatively defined, during rectal examination, by the tone at rest and the strength of a voluntary contraction, as strong, weak or absent. (NEW)

2.3 Pad testing may be used to quantify the amount of urine lost during incontinence episodes, and methods range from a short provocative test to a 24-hour pad test.

3. URODYNAMIC OBSERVATIONS AND CONDITIONS

3.1 Urodynamic Techniques

There are two principal methods of urodynamic investigation:

- **Conventional urodynamic studies** normally take place in the urodynamic laboratory and usually involve artificial bladder filling. (NEW)
- **Artificial bladder filling** is defined as filling the bladder, via a catheter, with a specified liquid at a specified rate. (NEW)
- **Ambulatory urodynamic studies** are defined as a functional test of the lower urinary tract, utilising natural filling, and reproducing the subject's every day activities.¹⁹
- **natural filling** means that the bladder is filled by the production of urine rather than by an artificial medium.

Both filling cystometry and pressure flow studies of voiding require the following measurements:

- **Intravesical pressure** is the pressure within the bladder. (ORIGINAL)
- **Abdominal pressure** is taken to be the pressure surrounding the bladder. In current practice it is estimated from rectal, vaginal or, less commonly from extraperitoneal pressure or a bowel stoma. The simultaneous measurement of abdominal pressure is essential for the interpretation of the intravesical pressure trace. (ORIGINAL)

¹⁹The term Ambulatory Urodynamics is used to indicate that monitoring usually takes place outside the urodynamic laboratory, rather than the subject's mobility using natural filling.

- **Detrusor pressure** is that component of intravesical pressure that is created by forces in the bladder wall (passive and active). It is estimated by subtracting abdominal pressure from intravesical pressure. (ORIGINAL)

3.2 Filling Cystometry

The word "cystometry" is commonly used to describe the urodynamic investigation of the filling phase of the micturition cycle. To eliminate confusion the following definitions are proposed:

- **Filling cystometry** is the method by which the pressure/volume relationship of the bladder is measured during bladder filling. (ORIGINAL)

The filling phase starts when filling commences and ends when the patient and urodynamicist decide that "permission to void" has been given.²⁰

Bladder and urethral function, during filling, need to be defined separately.

The rate at which the bladder is filled is divided into:

- **Physiological filling rate** is defined as a filling rate less than the predicted maximum - predicted maximum body weight in kg divided by 4, expressed as ml/min (17) (CHANGED)
- **Non-physiological filling rate** is defined as a filling rate greater than the predicted maximum filling rate - predicted maximum body weight in kg divided by 4, expressed as ml/min [Klevmark, 1999]. (CHANGED)

Bladder storage function should be described according to bladder sensation, detrusor activity, bladder compliance and bladder capacity.²¹

3.2.1 Bladder sensation during filling cystometry

- **Normal bladder sensation** can be judged by three defined points noted during filling cystometry and evaluated in relation to the bladder volume at that moment and in relation to the patient's symptomatic complaints.
 - **First sensation of bladder filling** is the feeling the patient has, during filling cystometry, when he/she first becomes aware of the bladder filling. (NEW)
 - **First desire to void** is defined as the feeling, during filling cystometry, that would lead the patient to pass urine at the next

²⁰The ICS no longer wishes to divide filling rates into slow, medium and fast. In practice almost all investigations are performed using medium filling rates which have a wide range. It may be more important during investigations to consider whether or not the filling rate used during conventional urodynamic studies can be considered physiological.

²¹Whilst bladder sensation is assessed during filling cystometry the assumption that it is sensation from the bladder alone, without urethral or pelvic components may be false.

convenient moment, but voiding can be delayed if necessary. (CHANGED)

- **Strong desire to void** this is defined, during filling cystometry, as a persistent desire to void without the fear of leakage. (ORIGINAL)
- **Increased bladder sensation** is defined, during filling cystometry, as an early first sensation of bladder filling (or an early desire to void) and/or an early strong desire to void, which occurs at low bladder volume and which persists. (NEW)²²
- **Reduced bladder sensation** is defined, during filling cystometry, as diminished sensation throughout bladder filling. (NEW)
- **Absent bladder sensation** means that, during filling cystometry, the individual has no bladder sensation. (NEW)
- **Non-specific bladder sensations**, during filling cystometry, may make the individual aware of bladder filling, for example, abdominal fullness or vegetative symptoms. (NEW)
- **Bladder pain**, during filling cystometry, is a self explanatory term and is an abnormal finding. (NEW)
- **Urgency**, during filling cystometry, is a sudden compelling desire to void. (NEW)²³
- **The vesical/urethral sensory threshold**, is defined as the least current which consistently produces a sensation perceived by the subject during stimulation at the site under investigation [Andersen et al., 1992]. (ORIGINAL)

3.2.2 Detrusor function during filling cystometry

In everyday life the individual attempts to inhibit detrusor activity until he or she is in a position to void. Therefore, when the aims of the filling study have been achieved, and when the patient has a desire to void, normally the 'permission to void' is given (see Filling Cystometry). That moment is indicated on the urodynamic trace and all detrusor activity before this 'permission' is defined as 'involuntary detrusor activity'.

- **Normal detrusor function:** allows bladder filling with little or no change in pressure. No involuntary phasic contractions occur despite provocation. (ORIGINAL)
- **Detrusor overactivity** is a urodynamic observation characterised by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked. (CHANGED)²⁴

There are certain patterns of detrusor overactivity:

- **Phasic detrusor overactivity** is defined by a characteristic wave form, and may or may not lead to urinary incontinence. (NEW)²⁵
- **Terminal detrusor overactivity** is defined as a single involuntary detrusor contraction occurring at cystometric capacity, which cannot be suppressed, and results in incontinence usually resulting in bladder emptying (voiding). (NEW)²⁶
- **Detrusor overactivity incontinence** is incontinence due to an involuntary detrusor contraction. (NEW)

In a patient with normal sensation urgency is likely to be experienced just before the leakage episode.²⁷

Detrusor overactivity may also be qualified, when possible, according to cause; for example:

- **Neurogenic detrusor overactivity** when there is a relevant neurological condition.

This term replaces the term "detrusor hyperreflexia". (NEW)

- **Idiopathic detrusor overactivity** when there is no defined cause. (NEW)

This term replaces "detrusor instability".²⁸

In clinical and research practice, the extent of neurological examination/investigation varies. It is likely that the proportion of neurogenic: idiopathic detrusor overactivity will increase if a more complete neurological assessment is carried out.

Other patterns of detrusor overactivity are seen, for example, the combination of phasic and terminal detrusor overactivity, and the sustained high pressure detrusor contractions seen in spinal cord injury patients when attempted voiding occurs against a dyssynergic sphincter.

- **Provocative manoeuvres** are defined as techniques used during urodynamics in an effort to provoke detrusor overactivity, for example, rapid filling, use of cooled

²²The assessment of the subject's bladder sensation is subjective and it is not, for example, possible to quantify "low bladder volume" in the definition of "increased bladder sensation".

²³The ICS no longer recommends the terms "motor urgency" and "sensory urgency". These terms are often misused and have little intuitive meaning. Furthermore, it may be simplistic to relate urgency just to the presence or absence of detrusor overactivity when there is usually a concomitant fall in urethral pressure.

²⁴There is no lower limit for the amplitude of an involuntary detrusor contraction but confident interpretation of low pressure waves (amplitude smaller than 5 cm H₂O) depends on "high quality" urodynamic technique. The phrase "which the patient cannot completely suppress" has been deleted from the old definition.

²⁵Phasic detrusor contractions are not always accompanied by any sensation, or may be interpreted as a first sensation of bladder filling, or as a normal desire to void.

²⁶"Terminal detrusor overactivity" is a new ICS term: it is typically associated with reduced bladder sensation, for example in the elderly stroke patient when urgency may be felt as the voiding contraction occurs. However, in complete spinal cord injury patients there may be no sensation whatsoever.

²⁷ICS recommends that the terms "motor urge incontinence" and "reflex incontinence", should no longer be used as they have no intuitive meaning and are often misused.

²⁸The terms "detrusor instability" and "detrusor hyperreflexia" were both used as generic terms, in the English speaking world and Scandinavia, prior to the first ICS report in 1976. As a compromise they were allocated to idiopathic and neurogenic overactivity respectively. As there is no real logic or intuitive meaning to the terms, the ICS believes they should be abandoned.

or acid medium, postural changes and hand washing. (NEW)

3.2.3. Bladder compliance during filling cystometry

- **Bladder compliance** describes the relationship between change in bladder volume and change in detrusor pressure. (CHANGED)²⁹

Compliance is calculated by dividing the volume change (ΔV) by the change in detrusor pressure (Δp_{det}) during that change in bladder volume ($C = V / \Delta p_{det}$). It is expressed in ml/cm H_2O .

A variety of means of calculating bladder compliance has been described. The ICS recommends that two standard points should be used for compliance calculations: the investigator may wish to define additional points. The standards points are:

1. the detrusor pressure at the start of bladder filling and the corresponding bladder volume (usually zero), and
2. the detrusor pressure (and corresponding bladder volume) at cystometric capacity or immediately before the start of any detrusor contraction that causes significant leakage (and therefore causes the bladder volume to decrease, affecting compliance calculation). Both points are measured excluding any detrusor contraction.

3.2.4. Bladder capacity: during filling cystometry

- **Cystometric capacity** is the bladder volume at the end of the filling cystometrogram, when "permission to void" is usually given. The end point should be specified, for example, if filling is stopped when the patient has a normal desire to void. The cystometric capacity is the volume voided together with any residual urine. (CHANGED)³⁰
- **Maximum cystometric capacity**, in patients with normal sensation, is the volume at which the patient feels he/she can no longer delay micturition (has a strong desire to void). (ORIGINAL)
- **Maximum anaesthetic bladder capacity** is the volume to which the bladder can be filled under deep general or spinal anaesthetic and should be qualified according to the type of anaesthesia used, the speed of filling, the length of time of filling, and the pressure at which the bladder is filled. (CHANGED)

²⁹The observation of reduced bladder compliance during conventional filling cystometry is often related to relatively fast bladder filling: the incidence of reduced compliance is markedly lower if the bladder is filled at physiological rates, as in ambulatory urodynamic.

³⁰In certain types of dysfunction, the cystometric capacity cannot be defined in the same terms. In the absence of sensation the cystometric capacity is the volume at which the clinician decides to terminate filling. The reason (s) for terminating filling should be defined, e.g. high detrusor filling pressure, large infused volume or pain. If there is uncontrollable voiding, it is the volume at which this begins. In the presence of sphincter incompetence the cystometric capacity may be significantly increased by occlusion of the urethra e.g. by Foley catheter.

3.2.5 Urethral function during filling cystometry

The urethral closure mechanism during storage may be competent or incompetent.

- **Normal urethral closure mechanism** maintains a positive urethral closure pressure during bladder filling even in the presence of increased abdominal pressure, although it may be overcome by detrusor overactivity. (CHANGED)
- **Incompetent urethral closure mechanism** is defined as one which allows leakage of urine in the absence of a detrusor contraction. (ORIGINAL)
- **Urethral relaxation incontinence** is defined as leakage due to urethral relaxation in the absence of raised abdominal pressure or detrusor overactivity. (NEW)³¹
- **Urodynamic stress incontinence** is noted during filling cystometry, and is defined as the involuntary leakage of urine during increased abdominal pressure, in the absence of a detrusor contraction. (CHANGED)

Urodynamic stress incontinence is now the preferred term to "genuine stress incontinence".³²

3.2.6. Assessment of urethral function during filling cystometry

- **Urethral pressure measurement**
 - **Urethral pressure** is defined as the fluid pressure needed to just open a closed urethra. (ORIGINAL)
 - **The urethral pressure profile** is a graph indicating the intraluminal pressure along the length of the urethra. (ORIGINAL)
 - **The urethral closure pressure profile** is given by the subtraction of intravesical pressure from urethral pressure. (ORIGINAL)
 - **Maximum urethral pressure** is the maximum pressure of the measured profile. (ORIGINAL)
 - **Maximum urethral closure pressure (MUCP)** is the maximum difference between the urethral pressure and the intravesical pressure. (ORIGINAL)
 - **Functional profile length** is the length of the urethra along which the urethral pressure exceeds intravesical pressure in women.
 - **Pressure "transmission" ratio** is the increment in urethral pressure on stress as a percentage of the simultaneously recorded increment in intravesical pressure.

³¹Fluctuations in urethral pressure have been defined as the "unstable urethra." However, the significance of the fluctuations and the term itself lack clarity and the term is not recommended by the ICS. If symptoms are seen in association with a decrease in urethral pressure a full description should be given.

³²In patients with stress incontinence, there is a spectrum of urethral characteristics ranging from a highly mobile urethra with good intrinsic function to an immobile urethra with poor intrinsic function. Any delineation into categories such as "urethral hypermobility" and "intrinsic sphincter deficiency" may be simplistic and arbitrary, and requires further research.

- **Abdominal leak point pressure** is the intravesical pressure at which urine leakage occurs due to increased abdominal pressure in the absence of a detrusor contraction. (NEW)³³
- **Detrusor leak point pressure** is defined as the lowest detrusor pressure at which urine leakage occurs in the absence of either a detrusor contraction or increased abdominal pressure. (NEW)³⁴
- **Flow time** is the time over which measurable flow actually occurs. (ORIGINAL)
- **Average flow rate** is voided volume divided by flow time. The average flow should be interpreted with caution if flow is interrupted or there is a terminal dribble. (CHANGED)
- **Time to maximum flow** is the elapsed time from onset of flow to maximum flow. (ORIGINAL)

3.3 Pressure Flow Studies

Voiding is described in terms of detrusor and urethral function and assessed by measuring urine flow rate and voiding pressures.

- **Pressure flow studies** of voiding are the method by which the relationship between pressure in the bladder and urine flow rate is measured during bladder emptying. (ORIGINAL)

The voiding phase starts when "permission to void" is given or when uncontrollable voiding begins, and ends when the patient considers voiding has finished.

3.3.1 Measurement of urine flow

Urine flow is defined either as **continuous**, that is with out interruption, or as **intermittent**, when an individual states that the flow stops and starts during a single visit to the bathroom in order to void. The continuous flow curve is defined as a **smooth arc shaped curve** or **fluctuating** when there are multiple peaks during a period of continuous urine flow.³⁵

- **Flow rate** is defined as the volume of fluid expelled via the urethra per unit time. It is expressed in ml/s. (ORIGINAL)
- **Voided volume** is the total volume expelled via the urethra. (ORIGINAL)
- **Maximum flow rate** is the maximum measured value of the flow rate after correction for artefacts. (CHANGED)
- **Voiding time** is total duration of micturition, i.e. includes interruptions. When voiding is completed without interruption, voiding time is equal to flow time. (ORIGINAL)

³³The leak pressure point should be qualified according to the site of pressure measurement (rectal, vaginal or intravesical) and the method by which pressure is generated (cough or valsalva). Leak point pressures may be calculated in three ways from the three different baseline values which are in common use: zero (the true zero of intravesical pressure), the value of p_{ves} measured at zero bladder volume, or the value of p_{ves} immediately before the cough or valsalva (usually at 200 or 300ml bladder capacity). The baseline used and the baseline pressure, should be specified.

³⁴Detrusor leak point pressure has been used most frequently to predict upper tract problems in neurological patients with reduced bladder compliance. ICS has defined it "in the absence of a detrusor contraction" although others will measure DLPP during involuntary detrusor contractions.

³⁵The precise shape of the flow curve is decided by detrusor contractility, the presence of any abdominal straining and by the bladder outlet. (11)

3.3.2. Pressure measurements during pressure flow studies (PFS)

The following measurements are applicable to each of the pressure curves: intravesical, abdominal and detrusor pressure.

- **Premicturition pressure** is the pressure recorded immediately before the initial isovolumetric contraction. (ORIGINAL)
- **Opening pressure** is the pressure recorded at the onset of urine flow (consider time delay). (ORIGINAL)
- **Opening time** is the elapsed time from initial rise in detrusor pressure to onset of flow. (ORIGINAL)

This is the initial isovolumetric contraction period of micturition. Flow measurement delay should be taken into account when measuring opening time.

- **Maximum pressure** is the maximum value of the measured pressure. (ORIGINAL)
- **Pressure at maximum flow** is the lowest pressure recorded at maximum measured flow rate. (ORIGINAL)
- **Closing pressure** is the pressure measured at the end of measured flow. (ORIGINAL)
- **Minimum voiding pressure** is the minimum pressure during measurable flow. This is not necessarily equal to either the opening or closing pressures.
- **Flow delay** is the time delay between a change in bladder pressure and the corresponding change in measured flow rate.

3.3.3. Detrusor function during voiding

- **Normal detrusor function**

Normal voiding is achieved by a voluntarily initiated continuous detrusor contraction that leads to complete bladder emptying within a normal time span, and in the absence of obstruction. For a given detrusor contraction, the magnitude of the recorded pressure rise will depend on the degree of outlet resistance. (ORIGINAL)

- **Abnormal detrusor activity can be subdivided:**

- **Detrusor underactivity** is defined as a contraction of xreduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to

achieve complete bladder emptying within a normal time span. (ORIGINAL)

- **Acontractile detrusor** is one that cannot be demonstrated to contract during urodynamic studies. (ORIGINAL)³⁶
- **Post void residual (PVR)** is defined as the volume of urine left in the bladder at the end of micturition. (ORIGINAL)³⁷

3.3.4. Urethral function during voiding

During voiding, urethral function may be:

Normal urethra function is defined as a urethra that opens, and is continuously relaxed to allow the bladder to be emptied at a normal pressure. (CHANGED)

Abnormal urethra function may be due to either obstruction to urethral overactivity, or a urethra that cannot open due to anatomic abnormality, such as an enlarged prostate or a urethral stricture.

- **Bladder outlet obstruction** is the generic term for obstruction during voiding and is characterised by increased detrusor pressure and reduced urine flow rate. It is usually diagnosed by studying the synchronous values of flowrate and detrusor pressure. (CHANGED)³⁸
- **Dysfunctional voiding** is defined as an intermittent and/or fluctuating flow rate due to involuntary intermittent contractions of the peri-urethral striated muscle during voiding, in neurologically normal individuals. (CHANGED)³⁹
- **Detrusor sphincter dyssynergia** is defined as a detrusor contraction concurrent with an involuntary contraction of the urethral and/or periurethral striated muscle. Occasionally flow may be prevented altogether. (ORIGINAL)⁴⁰
- **Non-relaxing urethral sphincter obstruction** usually occurs in individuals with a neurological lesion and is charac-

terised by a non-relaxing, obstructing urethra resulting in reduced urine flow. (NEW)⁴¹

4. CONDITIONS

- **Acute retention of urine** is defined as a painful, palpable or percussable bladder, when the patient is unable to pass any urine. (NEW)⁴²
- **Chronic retention of urine** is defined as a non-painful bladder, which remains palpable or percussable after the patient has passed urine. Such patients may be incontinent. (NEW)⁴³
- **Benign prostatic obstruction** is a form of *bladder outlet obstruction*; and may be diagnosed when the cause of outlet obstruction is known to be benign prostatic enlargement, due to histologic benign prostatic hyperplasia. (NEW)
- **Benign prostatic hyperplasia** is a term used (and reserved for) the typical histological pattern which defines the disease. (NEW)
- **Benign prostatic enlargement** is defined as prostatic enlargement due to histologic benign prostatic hyperplasia. The term "prostatic enlargement" should be used in the absence of prostatic histology. (NEW)

5. TREATMENT

The following definitions were published in the 7th ICS report on Lower Urinary Tract Rehabilitation Techniques (3) and remain in their original form.

5.1 Lower urinary tract rehabilitation is defined as non-surgical, non-pharmacological treatment for lower urinary tract function and includes;

- **Pelvic floor training** defined as repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles.
- **Biofeedback** is the technique by which information about a normally unconscious physiological process is presented to the patient and/or the therapist as a visual, auditory or tactile signal.
- **Behavioural modification** is defined as the analysis and alteration of the relationship between the patient's symptoms and his or her environment for the treatment of maladaptive voiding patterns.

³⁶ A normal detrusor contraction will be recorded as: a high pressure if there is high outlet resistance, normal pressure if there is normal outlet resistance; or low pressure if urethral resistance is low.

³⁷ If after repeated free flowmetry no residual urine is demonstrated, then the finding of a residual urine during urodynamic studies should be considered an artifact, due to the circumstances of the test.

³⁸ Bladder outlet obstruction has been defined for men but as yet, not adequately in women and children.

³⁹ Although dysfunctional voiding is not a very specific term it is preferred to terms such as "non-neurogenic neurogenic bladder". Other terms such as "idiopathic detrusor sphincter dyssynergia", or "sphincter overactivity voiding dysfunction", may be preferable. However, the term dysfunctional voiding is very well established. The condition occurs most frequently in children. Whilst it is felt that pelvic floor contractions are responsible, it is possible that the intra-urethral striated muscle may be important.

⁴⁰ Detrusor sphincter dyssynergia typically occurs in patients with a supra-sacral lesion, for example after high spinal cord injury and is uncommon in lesions of the lower cord. Although the intraurethral and periurethral striated muscles are usually held responsible, the smooth muscle of the bladder neck or urethra may also be responsible.

⁴¹ Non-relaxing sphincter obstruction is found in sacral and infra-sacral lesions such as meningocele, and after radical pelvic surgery. In addition there is often urodynamic stress incontinence during bladder filling. This term replaces "isolated distal sphincter obstruction".

⁴² Although acute retention is usually thought of as painful, in certain circumstances pain may not be a presenting feature, for example when due to prolapsed intervertebral disc, post partum, or after regional anaesthesia such as an epidural anaesthetic. The retention volume should be significantly greater than the expected normal bladder capacity. In patients after surgery, due to bandaging of the lower abdomen or abdominal wall pain, it may be difficult to detect a painful, palpable or percussable bladder.

⁴³ The ICS no longer recommends the term "overflow incontinence". This term is considered confusing and lacking a convincing definition. If used, a precise definition and any associated pathophysiology, such as reduced urethral function, or detrusor overactivity/low bladder compliance, should be stated. The term chronic retention, excludes transient voiding difficulty, for example after surgery for stress incontinence, and implies a significant residual urine; a minimum figure of 300mls has been previously mentioned.

This may be achieved by modification of the behaviour and/or environment of the patient.

5.2 Electrical stimulation is the application of electrical current to stimulate the pelvic viscera or their nerve supply.

The aim of electrical stimulation may be to directly induce a therapeutic response or to modulate lower urinary tract, bowel or sexual dysfunction.

5.3 Catheterization is a technique for bladder emptying employing a catheter to drain the bladder or a urinary reservoir.

5.3.1 Intermittent (in/out) catheterisation is defined as drainage or aspiration of the bladder or a urinary reservoir with subsequent removal of the catheter.

The following types of intermittent catheterization are defined:

- **Intermittent self-catheterisation** is performed by the patient himself/herself
- **Intermittent catheterisation** is performed by an attendant (e.g. doctor, nurse or relative)
- **Clean intermittent catheterisation:** use of a clean technique. This implies ordinary washing techniques and use of disposable or cleansed reusable catheters.
- **Aseptic intermittent catheterisation:** use of a sterile technique. This implies genital disinfection and the use of sterile catheters and instruments/gloves.

5.3.2 Indwelling catheterisation an indwelling catheter remains in the bladder, urinary reservoir or urinary conduit for a period of time longer than one emptying.

5.4 Bladder Reflex Triggering comprises various manoeuvres performed by the patient or the therapist in order to elicit reflex detrusor contraction by exteroceptive stimuli.

The most commonly used manoeuvres are; suprapubic tapping, thigh scratching and anal/rectal manipulation.

5.5 Bladder Expression comprises various manoeuvres aimed at increasing intravesical pressure in order to facilitate bladder emptying.

The most commonly used manoeuvres are abdominal straining, Valsalva's manoeuvre and Credé manoeuvre.

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ADDENDUM

Formation of the ICS Terminology Committee

The terminology committee was announced at the ICS meeting in Denver 1999 and expressions of interest were

invited from those who wished to be active members of the committee and they were asked to comment in detail on the preliminary draft (the discussion paper published in *Neurourology and Urodynamics*). The nine authors replied with a detailed critique by 1st April 2000 and constitute the committee: Paul Abrams, Linda Cardozo, Magnus Fall, Derek Griffiths, Peter Rosier, Ulf Ulmsten, Philip van Kerrebroeck, Arne Victor, and Alan Wein.

We thank other individuals who later offered their written comments: Jens Thorup Andersen, Walter Artibani, Jerry Blaivas, Linda Brubaker, Rick Bump, Emmanuel Chartier-Kastler, Grace Dorey, Clare Fowler, Kelm Hjalmas, Gordon Hosker, Vik Khullar, Guus Kramer, Gunnar Lose, Joseph Macaluso, Anders Mattiasson, Richard Millard, Rien Nijman, Arwin Ridder, Werner Schäfer, David Vodusek, and Jean Jacques Wyndaele.

A 1/2 day workshop was held at the ICS Annual Meeting in Tampere (August 2000) and a two-day meeting in London, January 2001, which produced draft 5 of the report which was then placed on the ICS website (www.icsoffice.org). Discussions on draft 6 took place at the ICS meeting in Korea September 2001, draft 7 then remained on the ICS website until final submission to journals in November 2001.

REFERENCES

- Abrams P (Chair), Blaivas JG, Stanton S, Andersen JT. 1988. ICS standardisation of terminology of lower urinary tract function. *Neurourol Urodyn* 7:403–26.
- Abrams P, Blaivas JG, Stanton SL, Andersen J. 1992. ICS 6th report on the standardisation of terminology of lower urinary tract function. *Neurourol Urodyn* 11:593–603.
- Andersen JT, Blaivas JG, Cardozo L, Thüroff J. 1992. ICS 7th report on the standardisation of terminology of lower urinary tract function: lower urinary tract rehabilitation techniques. *Neurourol Urodyn* 11:593–603.
- Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JOL, Klarskov P, Shull BL, Smith ARB. 1996. The standardisation of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol* 175:10–1.
- Fonda D, Resnick NM, Colling J, Burgio K, Ouslander JG, Norton C, Ekelund P, Versi E, Mattiasson A. 1998. Outcome measures for research of lower urinary tract dysfunction in frail and older people. *Neurourol Urodyn* 17:273–81.
- Griffiths D, Höfner K, van Mastrigt R, Rollema HJ, Spangberg A, Gleason D. 1997. ICS report on the standardisation of terminology of lower urinary tract function: pressure-flow studies of voiding, urethral resistance and urethral obstruction. *Neurourol Urodyn* 16:1–18.
- International Classification of Functioning, Disability and Health. ICIDH-2 website <http://www.who.int/icidh>.
- Klevmark B. 1999. Natural pressure: volume curves and conventional cystometry. *Scand J Urol Nephrol Suppl* 201:1–4.
- Lose G, Fanti JA, Victor A, Walter S, Wells TL, Wyman J, Mattiasson A. 1998. Outcome measures for research in adult women with symptoms of lower urinary tract dysfunction. *Neurourol Urodyn* 17:255–62.
- Lose G, Griffiths D, Hosker G, Kulseng-Hanssen S, Perucchini D, Schäfer W, Thind P, Versi E. Standardisation of urethral pressure measurement: report from the standardisation sub-committee of the International Continence Society. *Neurourol Urodyn* (In press).

- Mattiasson A, Djurhuus JC, Fonda D, Lose G, Nordling J, Stöhrer M. 1998. Standardisation of outcome studies in patients with lower urinary dysfunction: a report on general principles from the standardisation committee of the International Continence Society. *Neurourol Urodyn* 17:249–53.
- Nordling J, Abrams P, Ameda K, Andersen JT, Donovan J, Griffiths D, Kobayashi S, Koyanagi T, Schäfer W, Yalla S, Mattiasson A. 1998. Outcome measures for research in treatment of adult males with symptoms of lower urinary tract dysfunction. *Neurourol Urodyn* 17:263–71.
- Stöhrer M, Goepel M, Kondo A, Kramer G, Madersbacher H, Millard R, Rossier A, Wyndaele JJ. 1999. ICS report on the standardisation of terminology in neurogenic lower urinary tract dysfunction. *Neurourol Urodyn* 18:139–58.
- Schäfer W, Sterling AM, Liao L, Spangberg A, Pesce F, Zinner NR, van Kerrebroeck P, Abrams P, Mattiasson A. 2002. Good urodynamic practice: report from the standardisation sub-committee of the International Continence Society. *Neurourol Urodyn* In press.
- van Waalwijk van Doorn E, Anders K, Khullar V, Kulseng-Hansen S, Pesce F, Robertson A, Rosario D, Schäfer W. 2000. Standardisation of ambulatory urodynamic monitoring: report of the standardisation sub-committee of the International Continence Society for ambulatory urodynamic studies. *Neurourol Urodyn* 19:113–25.
- van Kerrebroeck P, Abrams P, Chaikin D, Donovan J, Fonda D, Jackson S, Jennum P, Johnson T, Lose G, Mattiasson A, Robertson G, Weiss J. 2002. ICS standardisation report on nocturia: report from the standardisation sub-committee of the International Continence Society. *Neurourol Urodyn* 21:193–99.
- wan D, James ED, Kramer AEJL, Sterling AM, Suhel PF. 1987. ICS report on urodynamic equipment: technical aspects. *J Med Eng Technol* 11(2):57–64.